

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM INTERNATIONAL)	
GMBH and BOEHRINGER INGELHEIM)	
PHARMACEUTICAL, INC.)	
)
Plaintiffs,)	C.A. No. 05-0700 (***)
)
v.)	
)
BARR LABORATORIES, INC.,)	
)
Defendant,)	
)
<hr/>	
BOEHRINGER INGELHEIM INTERNATIONAL)	
GMBH and BOEHRINGER INGELHEIM)	
PHARMACEUTICAL, INC.)	
)
Plaintiffs,)	C.A. No. 05-0854 (***)
)
v.)	
)
MYLAN PHARMACEUTICALS, INC.,)	
)
Defendant.)	

**PLAINTIFFS' BRIEF IN SUPPORT OF THEIR
MOTION TO STRIKE PORTIONS OF BARR'S EXPERT REPLY REPORTS**

MORRIS, NICHOLS, ARSH & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P. O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200

*Attorneys for Plaintiffs Boehringer
Ingelheim International GmbH and
Boehringer Ingelheim Pharmaceutical,
Inc.*

Of Counsel:

Steven C. Cherny
LATHAM & WATKINS LLP
885 Third Avenue, Suite 1000
New York, NY 10022-4834
(212) 906-1200

Kenneth G. Schuler
Amanda J. Hollis
Joel S. Neckers
LATHAM & WATKINS LLP
Sears Tower, Suite 5800
Chicago, IL 60606
(312) 876-7700

August 14, 2007

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	ii
NATURE AND STATE OF PROCEEDINGS.....	1
SUMMARY OF ARGUMENT	2
STATEMENT of FACTS	3
A. The Court's Scheduling Order	3
B. The Pertinent Expert Reports.....	4
1. Dr. Anslyn's Supplemental Report.....	4
2. Dr. Isenbruck's Report.....	7
3. Dr. Mailman's Report	10
ARGUMENT	11
CONCLUSION.....	16

TABLE OF AUTHORITIES

<u>Cases</u>	<u>Page</u>
<i>Avocent Huntsville Corp. v. ClearCube Tech., Inc.</i> , 443 F. Supp. 2d 1284 (N.D. Ala. 2006).....	15
<i>Baldwin Graphic Sys., Inc. v. Siebert, Inc.</i> , No. 03 C 7713, 2005 WL 1300763 (N.D. Ill. Feb. 22, 2005).....	14
<i>Finch v. Hercules, Inc.</i> , No. Civ. A. 92-251 MMS, 1995 WL 785100 (D. Del. Dec. 22, 1995)	12
<i>GSI Group, Inc. v. Sukup Mfg. Co.</i> , No. 05-3011, 2007 WL 757818 (C.D. Ill. March 8, 2007).....	15
<i>Graham v. Barolat</i> , C.A. No. 03-2029, 2005 U.S. Dist. LEXIS 644 (E.D. Pa. Jan. 12, 2005)	13
<i>Jarritos, Inc. v. Los Jarritos</i> , No. C 05-02380 JSW, 2007 U.S. Dist. LEXIS 32245 (N.D. Cal. May 2, 2007).....	15
<i>Johnson v. Vanguard Mfg., Inc.</i> , 34 Fed. Appx. 858 (3d Cir. 2002).....	12
<i>Konstantopoulos v. Westvaco Corp.</i> , 112 F.3d 710 (3d Cir. 1997).....	12-14
<i>Mason v. Smithkline Beecham Corp.</i> , No. 05-CV-1252, 2007 U.S. Dist. LEXIS 21147 (C.D. Ill. March 26, 2007)	15
<i>Micro Int'l, Ltd. v Monolithic Power Sys.</i> , 467 F.3d 1355 (Fed. Cir. 2006).....	12
<i>Praxair, Inc. v. ATMI, Inc.</i> , 231 F.R.D. 457 (D. Del. 2003)	12
<i>Trilogy Communs., Inc. v. Times Fiber Communs., Inc.</i> , 109 F.3d 739 (Fed. Cir. 1997).....	15
<i>United States v. 68.94 Acres of Land</i> , 918 F.2d 389 (3d Cir. 1990).....	12

Statutes

21 U.S.C. § 355(j)(2)(A)(vii)(IV)	1
35. U.S.C. § 112.....	5

Federal Rules

Fed. R. Civ. P. 26.....	<i>passim</i>
Fed. R. Civ. P. 37.....	12

NATURE AND STATE OF PROCEEDINGS

Plaintiffs Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (“Plaintiffs” or “Boehringer”) filed this lawsuit on September 26, 2005, after Barr Laboratories, Inc. (“Barr”) submitted an ANDA seeking approval to sell a generic version of Boehringer’s successful drug MIRAPEX® and submitted a paragraph IV certification relating to the patents listed by Boehringer in the FDA’s “Orange Book.” *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Barr filed an Answer, Separate Defenses and Counterclaims to Boehringer’s Complaint (D.I. 8).¹

Boehringer is the owner of United States Patent No. 4,866,812 (“the ‘812 patent”), which is the subject of the instant litigation. The ‘812 patent relates to a compound called pramipexole, which is used, among other things, in the treatment of Parkinson’s disease and Restless Leg Syndrome. Boehringer sells a product containing pramipexole called MIRAPEX. The ‘812 patent claims priority to two German applications (the “German priority applications”).

Barr is seeking to manufacture and market a generic version of MIRAPEX (“Barr’s product”), the active ingredient of which is pramipexole, prior to the expiration of the ‘812 patent. Boehringer has asserted that Barr’s ANDA filing constitutes infringement of various claims of the ‘812 patent. Barr has not contested infringement of six of the seven asserted claims of the ‘812 patent. Instead, Barr has asserted that: (i) the claims in the ‘812 patent are invalid for double patenting; (ii) that “new matter” allegedly was added to the ‘812

¹ Boehringer also filed suit against Mylan Pharmaceuticals, Inc. (“Mylan”), which was consolidated with the lawsuit filed against Barr for purposes of discovery. Mylan has adopted the expert reports submitted by Barr in this case.

patent during its prosecution, such that two of the claims of the ‘812 patent are not entitled to the priority date of the German priority applications and allegedly thereby anticipated by the work of scientists at Eli Lilly & Co (“Eli Lilly”); and (iii) that Dr. Rolf Fleischer (formerly Boehringer’s German patent counsel) purportedly committed inequitable conduct in connection with the prosecution of the ‘812 patent.

Boehringer bears the burden of proof on issues related to the infringement of the ‘812 patent, while Barr bears the burden of proof on validity and inequitable conduct. Fact discovery closed on January 23, 2007, and the parties are presently engaged in expert discovery.

SUMMARY OF ARGUMENT

Expert disclosures must be made “at the times and in the sequence directed by the court,” and such disclosures must contain “a complete statement of all opinions to be expressed and the basis and reasons therefore.” FED. R. CIV. P. 26. In this case, the Court set March 28, 2007, as the deadline for serving all expert disclosures regarding issues on which a party bears the burden of proof. Given the parties’ respective burdens, Boehringer was required to serve any expert opinions relating to infringement on that date, while Barr was required to do so with regard to its invalidity and inequitable conduct defenses.

Barr served three expert reports on March 28, 2007 which, per the applicable provisions of the FEDERAL RULES OF CIVIL PROCEDURE, set the boundaries of the experts’ testimony on direct examination. On July 9, 2007, Barr served three additional expert reports that purport to “supplement” its initial expert reports and respond to the expert reports Boehringer served on May 18, 2007. Those reports, however, contain a number of new opinions that cannot be characterized as “replying” to anything. Indeed, Barr’s “reply” reports contain a

number of opinions that come out of nowhere and address for the first time issues on which Barr bears the burden of proof. Barr's attempt to submit opinion testimony on topics upon which Barr bears the burden of proof under the guise of "reply" expert reports violates both the Court's Scheduling Order and the applicable provisions of the FEDERAL RULES OF CIVIL PROCEDURE in a manner that is plainly prejudicial to Boehringer. Under settled law and the Court's Scheduling Order, a number of paragraphs in Barr's reply reports are improper and should be stricken.

STATEMENT OF FACTS

A. The Court's Scheduling Order

The Court's March 8, 2007 Scheduling Order required the parties to "serve their Federal Rule of Civil Procedure 26(a)(2) disclosures of expert testimony on all issues for which a party bears the burden of proof on or before March 28, 2007." Scheduling Order, Ex. A hereto, D.I. 135. The Court's Scheduling Order, as amended, set May 18, 2007 as the date by which the parties were to serve their disclosures to rebut or contradict evidence on the same subject matter. *See id.* The parties agreed that the party bearing the burden of proof on an issue could submit supplemental disclosures to reply on the same subject matter on or before July 9, 2007. *See id.* There is no provision allowing Boehringer to respond to Barr's reply reports.

On March 28, 2007, Barr served expert reports from Dr. Eric V. Anslyn, Dr. Walter G. Chambliss, and Dale H. Hoscheit.² On the same day, Boehringer served the expert report of Dr. Alexander Klibanov addressing the infringement of the '812 patent. On May 18, 2007, Boehringer served four expert reports relating to issues upon which Barr bears the burden of proof. Boehringer's submissions included reports from Dr. C. Warren Olanow, Walter

² Boehringer has moved to strike Mr. Hoscheit's expert report in its entirety. (D.I. 153).

Holzer, Dr. Paul Bartlett, and Dr. Mohan Rao. On July 9, 2007, Barr served its reply reports, including a “supplemental” report from Dr. Anslyn and reports from Gunter Isenbruck and Dr. Richard Mailman. On July 19, 2007, per agreement by the parties, Barr served an additional expert report, from Roy Weinstein.

B. The Pertinent Expert Reports

1. Dr. Anslyn’s Supplemental Report

Barr bears the burden of establishing its invalidity defenses at trial. Barr submitted an expert report from Dr. Anslyn, a chemistry professor, on March 28, 2007, apparently in support of certain of its defenses. *See Anslyn Report, Ex. B hereto.* Notably, Dr. Anslyn does not opine that any claim of the ‘812 patent is invalid for any reason. Instead, Dr. Anslyn offers “opinions” that in effect recite his understanding of various predicate facts relating to certain aspects of Barr’s invalidity contentions. *See id. at passim.*

For instance, Dr. Anslyn generally opines that “the compounds in claims 3-5 and 7-10 of the ‘812 patent are identical to or completely encompass the compounds used in method claims of the ‘086 patent,” (*see Anslyn Report, Ex. B hereto at ¶¶ 17, 37-39*), but does not assert that any claim is invalid for obviousness-type double patenting. *See id.* Indeed, the question as to whether the claims of the ‘812 patent are invalid for double patenting was not one that Barr asked Dr. Anslyn to address. *See id. at ¶ 12.*

Second, Dr. Anslyn offers opinions about “General Formula I” in the ‘812 patent. *See id. at ¶¶ 40-47.* Specifically, Dr. Anslyn opines that “[t]he definition of R₁ in General Formula I of the ‘812 patent . . . is broader than the definition of R₁ set forth in the ‘075 and ‘947 German applications.” *Id. at ¶ 45.* Dr. Anslyn does not even purport to analyze whether

the '812 patent claims satisfy the written description requirement of 35 U.S.C. § 112, however. *See id.* at *passim*. Indeed, it appears that Barr has not asked Dr. Anslyn to provide any written opinion on that subject. *See id.* at ¶ 12 (setting for the topics upon which Dr. Anslyn has been asked to opine).

Finally, Dr. Anslyn offers “opinions” summarizing work performed by certain Eli Lilly scientists (*i.e.*, asserting that they “successfully prepared” certain compounds prior to December 22, 1984) and asserts that various, later-filed Lilly patent applications “disclose and contain claims that the skilled artisan would understand encompass” those compounds. *See id.* at ¶¶ 48-57. Dr. Anslyn does not analyze whether or not the activity of the Eli Lilly scientists constitutes “prior invention” under § 102(g), nor does he otherwise explain how his opinions bear upon any issue in the litigation. *See id.* at *passim*.

Boehringer subsequently served a report from Dr. Paul Bartlett addressing certain of Barr’s invalidity defenses. *See* Bartlett Report, Ex. C hereto. Dr. Bartlett, Emeritus Professor of Chemistry at the University of California-Berkeley, specifically was asked by Boehringer to address the merits of Barr’s alleged “new matter” and § 102(g) defenses. With regard to the former, Dr. Bartlett notes that:

Dr. Anslyn has focused narrowly on the definition of the genus of compounds in Claim 1. He has not, as I understand the law requires, properly analyzed the application as a whole, which not only discloses synthetic methods that produce those compounds but also describes starting materials and synthetic intermediates that would reasonably lead one of skill in the art to them.

Bartlett Rept. at ¶ 85. Analyzing Barr’s new matter defense under the framework of § 112, Dr. Bartlett concludes that:

In my opinion, the first German priority application adequately discloses to one of skill in the art the halogenated phenyl alkyl R₁ derivatives to meet the written description requirement of U.S. patent law.

Id. at ¶¶ 16.

Dr. Bartlett was also asked to analyze whether the work of Eli Lilly scientists constituted “prior invention” within the ambit of § 102(g), and concluded that it did not:

My analysis of the evidence concerning the work performed at Lilly by Dr. Bennett Laguzza and Mr. William Turner, Jr. shows that it does not constitute invention of 2-amino-6-dipropylamino-4,5,6,7-tetrahydrobenzthiazole, 2-amino-6-di-methylamino-4,5,6,7-tetrahydrobenzthiazole, and 2-methylamino-6-di-methylamino-4,5,6,7-tetrahydrobenzthiazole prior to June 19, 1985.

Id. at ¶ 15.

Barr subsequently served a supplemental report from Dr. Anslyn in which Dr. Anslyn purports to respond to Dr. Bartlett’s opinions. *See* Anslyn Supp. Report, Ex. D hereto. Rather than respond, however, for the most part, Dr. Anslyn’s supplemental report contains wholly new opinions – some of which improperly attempt to fill the holes in Dr. Anslyn’s initial report, and some of which concern completely new topics.

For example, Dr. Anslyn’s Supplemental Report includes a Section B, in which Dr. Anslyn variously opines that “each of claims 3-5 and 9-10 of the ‘812 patent encompasses multiple different compounds,” that claim 8 in the ‘812 patent encompasses “at least thousands of pharmaceutical compositions,” and that practicing the methods of certain claims of the ‘086 patent would lead to the formation of certain compounds “in both protonated (acidic) and unprotonated (free base) form.” *See* Anslyn Supp. Report at ¶¶ 14-16. While it is unclear whether the foregoing topics relate to validity of the ‘812 patent, to the extent that they do, they

were not included in Dr. Anslyn's initial report and do not respond to Dr. Bartlett's opinions.

Compare id. with Dr. Bartlett's Report, Ex. C hereto.

Dr. Anslyn's supplemental report also interjects a number of new opinions in alleged support of Barr's "new matter" theory. Those opinions go beyond the narrowly-circumscribed opinions Dr. Anslyn offered in his initial report. *See* Anslyn Supp. Report at ¶¶ 9-13. As noted, Dr. Anslyn did not analyze the "entire disclosure" of the German Priority applications, focusing instead on only a single part (General Formula I) and ignoring entirely the sections of those applications detailing methods for synthesizing compounds within the scope of the invention. *See* disc. *supra* at 6, 7. In his Supplemental Report, Dr. Anslyn for the first time opines on how one of skill in the art would read various sections of the specification, arguing, for instance that the:

"wherein at least one of the groups R₁, R₂, R₃ or R₄..." clause in the first sentence would be understood by a skilled artisan to indicate that the method is directed to making compounds defined by General Formula I, not a broad group of compounds unlimited by the bounds of General Formula I.

Id. at ¶ 9.

2. Dr. Isenbruck's Report

Barr has alleged that the '812 patent is invalid due to inequitable conduct during its prosecution, and Barr bears the burden of proof on this defense. In the initial round of expert reports, Barr served the report of Mr. Hoscheit, a U.S. patent attorney. *See* Hoscheit Report, Ex. E hereto. As noted in Boehringer's pending Motion to Strike Mr. Hoscheit's Report, Mr. Hoscheit improperly attempts to opine that Boehringer's statements regarding the effective filing date of the '812 patent were "inaccurate" and "material." *See* (D.I. 153). However, Mr.

Hoscheit's report does not address European or German patent practice, much less the understanding of U.S. priority law by a European or German patent practitioner in the 1980s.

See id.

Though Boehringer did not bear the burden of proof on the issue, and Boehringer believes that Barr failed to submit any admissible expert opinion on the subject, on March 28, 2007, Boehringer served a report from Mr. Holzer, an Austrian and European patent attorney. *See Holzer Report, Ex. F hereto.* In his report, Mr. Holzer offers two general categories of opinions. First, Mr. Holzer opines about the differences between European and United States patent law ("Section III"). *See id.* at ¶¶ 12-25. In Section III, Mr. Holzer explains several fundamental differences between European and United States patent law, including the appropriateness of claiming priority to previous patent applications under European patent law.

See id.

Second, Barr's previous pleadings claimed that Dr. Fleischer allegedly made a knowing misrepresentation regarding entitlement to priority, identifying his purported participation in compiling foreign filing information, which included a document indicating that priority for the underlying U.S. '947 application could be claimed to both German Priority Applications. Mr. Holzer opines that Boehringer's pattern of filings was "entirely normal" and that Boehringer's prosecution of the '812 patent was "consistent with general practices." *See id.* at ¶¶ 30, 32. Mr. Holzer further opines that:

From a European patent prosecution perspective, even assuming that there was a claim in the foreign filing that was broader than the disclosure in the priority application, it would still be appropriate to claim priority.

Id. at ¶ 34.

After Boehringer served the report of Mr. Holzer, Barr served the purported “reply” report of Mr. Isenbruck, a European and German patent attorney. *See* Isenbruck Report, Ex. G hereto. Mr. Isenbruck devotes virtually the entirety of his report to opining about a European or German patent practitioner’s understanding of European priority law, even though Barr submitted no such opinions in connection with its initial expert disclosures, and even though Barr bears the burden of proof on inequitable conduct. *See id.* at ¶¶ 17-24. By way of example, Mr. Isenbruck opines that after comparing the claims in the German applications with their European counterpart, “a European patent practitioner . . . would understand that it is not correct to state that such claims or the European application itself have an effective filing date that is identical to the filing date of the German application.” *See id.* at ¶ 21. By way of further example, Mr. Isenbruck opines that in light of differences between U.S and European patent law,

a practitioner who was aware that multiple priority dates were involved in the European prosecution would, upon seeing a statement in connection with the prosecution of a U.S. counterpart application that the application had an “effective filing date” of the earlier priority document, alert his U.S. correspondence attorney [...] that, at least under European law, not all of the claimed subject matter had a priority date of the earlier application.

Id. at ¶ 22. Finally, Mr. Isenbruck opines that the “discovery of the Eli Lilly U.S. application is precisely the kind of event that would cause a European or German patent practitioner to assess the distribution of different priorities with respect to different claims.” *See id.* at ¶ 23.

According to Barr, the opinions set forth in Mr. Isenbruck’s report allegedly constitute affirmative support for Barr’s inequitable conduct defense. As Barr said in a recent filing, it intends to rely upon Mr. Isenbruck’s report as supposed support for the notion that, *inter alia*, “the statement concerning Boehringer’s effective filing date would be incorrect . . .

and that a European or German practitioner . . . would be aware of the misrepresentation.” See Reply Brief In Support Of Defendant Barr Laboratories, Inc.’s Motion For In Camera Inspection And To Compel Production Of Documents Pursuant To The Crime-Fraud Exception (D.I. 165).

3. Dr. Mailman’s Report

Though Barr failed to serve any expert report including an opinion that any claim of the ‘812 patent is invalid for obviousness-type double patenting, Boehringer served two expert reports directed to secondary indicia of non-obviousness, including a report from Dr. Warren Olanow, the Chairman of the Department of Neurology and Chief of the Neurology Service at Mount Sinai Medical Center. *See* Olanow Report, Ex. H hereto. In his report, Dr. Olanow addressed whether certain uses for which MIRAPEX® is prescribed would not have been expected or predictable from the uses claimed in the ‘086 patent, and that such additional uses met long-felt but unmet needs that were not satisfactorily addressed by therapeutic agents available as of the filing date of the ‘812 patent. *See id.* at ¶¶ 16-48. Dr. Olanow’s Report makes no reference to the Eli Lilly work upon which Barr’s Section 102(g) defense is premised. *See id. at passim.*

Barr then served the report of Dr. Mailman, purportedly to “comment on and respond to issues raised by Dr. C. Warren Olanow’s report,” but also “to address issues related to experiments disclosed in the Eli Lilly U.S. Application Serial No. 747,748.” *See* Mailman Report, Ex. I hereto at ¶ 15. To the extent that Dr. Mailman’s opinions address the opinions offered by Dr. Olanow, Boehringer does not object to them.

Section V of Dr. Mailman’s Report (comprising Paragraphs 35 and 36), however, has nothing to do with rebutting Dr. Olanow’s opinions. That section instead was included “to

address issues related to experiments disclosed in the Eli Lilly U.S. Application Serial No. 747,748.” *See Mailman Report, Ex. I hereto at ¶ 15.* For instance, Dr. Mailman opines that Eli Lilly scientists synthesized compounds claimed in the ‘812 patent prior to its effective filing date and that in the 1980s and today, “a compound that was expected to possess dopamine agonist activity would also be expected to be useful in connection with the treatment of parkinsonism or Parkinson’s disease.” *See id. at ¶¶ 35, 36.* Section V of Dr. Mailman’s is not responsive to Dr. Olanow’s report, and plainly relates to an issue on which Barr bears the burden of proof. *See Mailman Report, Ex. I hereto ¶¶ at 35-36.*

For the reasons set forth below, the entirety of the Isenbruck Report, Section V of Dr. Mailman’s Report, and Paragraphs 4-16 of the Supplemental Anslyn Report should be stricken.

ARGUMENT

Under FEDERAL RULE OF CIVIL PROCEDURE 26(a)(2)(C), expert disclosures must be made “at the times and in the sequence directed by the court,” and pursuant to Rule 26(a)(2)(B), such disclosures must contain “a complete statement of all opinions to be expressed and the basis and reasons therefore.” FED. R. CIV. P. 26(a)(2)(C) & 26(a)(2)(B). Pursuant to the Court’s Scheduling Order, the timing of expert disclosure obligations hinged upon the allocation of the burden of proof, as logically “the party with the burden of proof on an issue should disclose its expert testimony on that issue before other parties are required to make their disclosures with respect to that issue.” FED. R. CIV. P. 26, 1993 Adv. Comm. Note.

In light of the requirements set forth in Rule 26(a)(2), the provisions of the Scheduling Order required Barr’s invalidity and unenforceability experts to provide a complete

statement of their opinions and the bases therefore – in other words, “the testimony the witness is expected to present during direct examination,” (FED. R. CIV. P. 26, 1993 Adv. Comm. Note) – no later than March 28, 2007. *See* disc. *supra* at 5, 6, 13. “Fidelity to the constraints of Scheduling Orders and deadlines is critical to the Court’s case management responsibilities.” *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 464 (D. Del. 2003); *Finch v. Hercules, Inc.*, No. Civ. A. 92-251 MMS, 1995 WL 785100 at *9 (D. Del. Dec. 22, 1995). If an expert’s initial report does not include a complete statement of opinions to be expressed and the basis for these opinions, a court may prohibit the expert from later testifying on issues or opinions not addressed in the initial report. *See* FED. R. CIV. P. 37(c)(1); *Johnson v. Vanguard Mfg., Inc.*, 34 Fed. Appx. 858, 859 (3d Cir. 2002); *United States v. 68.94 Acres of Land*, 918 F.2d 389, 396 (3d Cir. 1990) (noting that the court is authorized to exclude evidence proffered by the disobedient party as a sanction for failure to comply with the scheduling order); *Micro Int’l, Ltd. v Monolithic Power Sys.*, 467 F.3d 1355, 1363 (Fed. Cir. 2006). Indeed, as the Advisory Committee Notes to Rule 26(a)(2) explain, in light of Rule 37(c)(1), “a party will not ordinarily be permitted to use on direct examination any expert testimony not so disclosed.” FED. R. CIV. P. 26, 1993 Adv. Comm. Note.

Under Third Circuit law, the decision whether to strike expert opinions for failure to comply with the Scheduling Order involves a consideration of (1) “the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified,” (2) “the ability of that party to cure the prejudice,” (3) “the extent to which waiver of the rule [at issue] would disrupt the orderly and efficient trial of the case or of other cases in the court,” and (4) “bad faith or willfulness in failing to comply with the court’s order.” *Konstantopoulos v. Westvaco Corp.*,

112 F.3d 710, 719 (3d Cir. 1997) (citations omitted); *Graham v. Barolat*, C.A. No. 03-2029, 2005 U.S. Dist. LEXIS 644 (E.D. Pa. Jan. 12, 2005). Each of those factors favors the exclusion of the entirety of the Isenbruck Report, Section V of Dr. Mailman's Report, and Paragraphs 4-16 of the Supplemental Anslyn Report.

Initially, there is no legitimate dispute that Barr has submitted three "supplemental" expert reports (1) concerning issues upon which Barr bears the burden of proof, and (2) including opinions absent from Barr's initial expert disclosures. *See disc. supra* at 5-13. Moreover, none of those "supplemental" opinions is even purportedly based on any new information; rather, they are premised on information available to Barr at the time it served its initial reports. *See id.* Accordingly, the entirety of the Isenbruck Report, Section V of Dr. Mailman's Report, and Paragraphs 4-16 of the Supplemental Anslyn Report should have been included in Barr's initial expert disclosures per the unambiguous provisions of the Court's Scheduling Order. *See* March 8, 2007 Scheduling Order (D.I. 135) at ¶ 3 ("the parties shall serve their Federal Rule of Civil Procedure 26(a)(2) disclosures of expert testimony on all issues for which a party bears the burden of proof on or before March 28, 2007"). The three supplemental expert reports at issue therefore plainly violate the Court's Scheduling Order.

The Court should strike the above-noted paragraphs from Barr's reply reports. *See, e.g., Konstantopoulos*, 112 F.3d 710, 719. First, there can be no doubt that the new opinions offered in Barr's reply reports were late, and that Boehringer will be prejudiced by the inclusion of Barr's supplemental expert testimony, as Boehringer will have to devote substantial time and resources to litigating entirely new theories that should have been disclosed over four months ago. Boehringer also will be prejudiced because it has no opportunity to procure expert

testimony to address those newly-advanced theories. For that reason, unless the offending reports are stricken, Barr will be in a strategically better position than if it *had* complied with the Court's Order and timely disclosed such opinions in March. A party should hardly profit from disregarding this Court's directives.

Second, Boehringer cannot cure such prejudice. Because they were disclosed entirely out of time – at the end of the expert disclosure process, rather than at the beginning – Boehringer has no opportunity to respond to any of the new opinions set forth in Barr's reply reports. Nor can Boehringer adequately prepare to address those opinions given that they were served over four months after the deadline and in light of the September 14th deadline for the conclusion of expert discovery.

Third, Barr's decision to flout the applicable provisions of the Court's Scheduling Order has disrupted the orderly and efficient trial of this case, as the parties are embarking on expert depositions and there is no time built into the Court's Scheduling Order to rebut the new opinions included in Barr's reply reports. *See id.*

Finally, Barr willfully failed to comply with the Court's Scheduling Order. *See Konstantopoulos*, 112 F.3d at 719; *see also, e.g., Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, No. 03 C 7713, 2005 WL 1300763 (N.D. Ill. Feb. 22, 2005). Barr has provided no justification for its conduct. Given that the information upon which those opinions are premised was available as of March 28, 2007, they could have been timely presented.

Courts routinely strike expert opinions in such circumstances. Thus, in, *Baldwin*, the court stated:

The rebuttal expert report is no place for presenting new arguments
Defendant had the burden to prove that the patents-in-suit are invalid for

obviousness or anticipation, if it chose to pursue those arguments, and arguments to that extent should have been included in its initial report. Defendant thus attempts, without justification, to supplement its initial report with opinions presented in its rebuttal reports.

2005 WL 1300763. The court struck the portions of the rebuttal report that it determined should have been disclosed in the defendant's initial expert report, noting that "Defendant deliberately chose not to [allege invalidity or anticipation] in its initial report, just as it purposely chose to in its rebuttal report." *See id.*

Likewise, in *Trilogy Communs., Inc. v. Times Fiber Communs., Inc.*, 109 F.3d 739, 744-745 (Fed. Cir. 1997), Trilogy belatedly submitted expert reports containing new opinions and that did not merely supplement the expert's original report. *See id.* The Federal Circuit upheld the district court's decision to strike the portions of the reports containing such improper "supplemental" opinions. *See id.*; *see also GSI Group, Inc. v. Sukup Mfg. Co.*, No. 05-3011, 2007 WL 757818 (C.D. Ill. March 8, 2007) (striking a number of opinions in a supplemental expert report that were not disclosed in the initial report); *Mason v. Smithkline Beecham Corp.*, No. 05-CV-1252, 2007 U.S. Dist. LEXIS 21147 (C.D. Ill. March 26, 2007) (striking portions of supplemental report that could have been included in original report); *Jarritos, Inc. v. Los Jarritos*, No. C 05-02380 JSW, 2007 U.S. Dist. LEXIS 32245 (N.D. Cal. May 2, 2007) (striking portions of rebuttal reports where even though each report was entitled "rebuttal," the substance of the reports did not actually rebut or even directly address the opinions of the opposing party's expert); *Avocent Huntsville Corp. v. ClearCube Tech., Inc.*, 443 F. Supp. 2d 1284, 1308 (N.D. Ala. 2006) (striking portions of supplemental expert report that extended beyond the limited subject matter incorporated into experts' analysis regarding

invalidity in opening report). Accordingly, the paragraphs of Barr's expert reports, discussed above, should be stricken.³ *See id.*

CONCLUSION

For the reasons set forth above, Borheinger respectfully requests that the Court strike the entirety of the Isenbruck Report, Section V of Dr. Mailman's Report, and Paragraphs 4-16 of the Supplemental Anslyn Report.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
 Maryellen Noreika (#3208)
 1201 North Market Street
 P. O. Box 1347
 Wilmington, DE 19899-1347
 (302) 658-9200
mmoreika@mnat.com

*Attorneys for Plaintiffs
 Boehringer Ingelheim International GmbH
 and Boehringer Ingelheim
 Pharmaceuticals, Inc.*

Of Counsel:

Steven C. Chemy
 LATHAM & WATKINS LLP
 885 Third Avenue, Suite 1000
 New York, NY 10022-4834
 (212) 906-1200

³ To the extent that the Court does not strike the opinions addressed above, in the alternative, Boehringer requests the Court to allow Boehringer to serve supplemental reports to respond to the new opinions set forth in the various "supplemental" reports as a matter of fundamental fairness.

Kenneth G. Schuler
Amanda J. Hollis
Joel S. Neckers
LATHAM & WATKINS LLP
Sears Tower, Suite 5800
Chicago, IL 60606
(312) 876-7700

August 14, 2007
1210345

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that on August 14, 2007, 2006, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send notification of such filing to the following:

Mary B. Matterer
Morris James LLP

Adam Wyatt Poff
Young, Conaway, Stargatt & Taylor LLP

I further certify that copies of the foregoing document were also served upon the following in the manner indicated:

BY HAND DELIVERY

Mary B. Matterer, Esquire
Morris James LLP
500 Delaware Avenue
Wilmington, DE 19801

Adam Wyatt Poff, Esquire
Young, Conaway, Stargatt & Taylor LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801

BY FEDERAL EXPRESS

Glenn J. Pfadenhauer, Esquire
Jessamyn S. Berniker, Esquire
Dov P. Grossman, Esquire
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005-5901

Shannon M. Bloodworth, Esquire
Heller Ehrman LLP
1717 Rhode Island Ave., NW
Washington, DC 20036

David J. Harth, Esquire
Heller Ehrman LLP
One East Main Street, Suite 201
Madison, WI 53703

/s/ Maryellen Noreika

Maryellen Noreika (#3208)